Attachment II 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number:_____

1. Date of Submission: October 29, 2012

2. Sponsor Identification

Shenzhen Delicate Electronics Co., Ltd.
6C, Block 8, Tian-an Ind. Area, Nanshan District
Shenzhen, Guangdong, 518054, China

Establishment Registration Number: 3006441164

Contact Person: Min Li
Position: General Manager
Tel: +86-755-26413482
Fax: +86-755-26425970
Email: minnli@delica-sz.com

3. Submission Correspondent

Ms. Diana Hong & Mr. Lee Fu
Mid-Link Consulting Co., Ltd
P.O. Box 237-023
Shanghai, 200237, China
Tel: +86-21-22815850
Fax: 240-238-7587
Email: info@mid-link.net

4. Type and Reason of Submission

Special 510(k) Submission for the design change to the existed device, which is EMS9UA Transcranial Doppler with Robotic Probe Headband as cleared in K092164.

5. Proposed Device Identification

Proposed Device Name: Transcranial Doppler with Robotic Probe Headband
Proposed Device Model: EMS9UA, EMS 9PB

Classification: Class II
Product Codes: IYN, ITX and OQQ
Regulation Number: 21 CFR 892.1570
Review Panel: Radiology

Intended Use Statement:
Transcranial Doppler Ultrasound System is intended for use as a diagnostic ultrasound fluid flow analysis system:

1) For the measurement of cerebral artery blood velocities to determine the presence of hemo dynamically significant deviations from normal values;
2) To assess arterial cerebral blood flow for the occurrence of micro embolic signals. Vessels intended for observation include, but are not limited to the middle, anterior and posterior cerebral arteries, via the temporal windows, the vertebral mid basilar arteries via the foramen magnum and the ophthalmic artery and intracranial internal carotid artery via the eye.

The Roboprobe Headband facilitates monitoring use by its ability to track the Doppler signal.
Transcranial Doppler is intended for use during:

1) Diagnostic exams;
2) Surgical interventions.

The device is not intended to replace other means of evaluating vital patient physiological processes, is not intended to be used in fetal applications, and is not intended to be used inside the sterile field.

6. Predicate Device Identification

510(k) Number: K092164
Product Name: EMS9UA Transcranial Doppler with Robotic Probe Headband
Manufacturer: Shenzhen Delicate Electronics Co., Ltd.

7. Device Description

The proposed device,Transcranial Doppler (TCD) with Robotic Probe Headband,is intended for obtaining the information of blood flow velocities throughout the body by using non-invasive technique. This method of measurement is particularly useful for examining the major arteries supplying blood to the brain.

Robotic Probe is developed by Delicate for monitoring brain blood application. It was previously cleared in K092164 at May 10, 2010. The system can adjust the angle of probe automatically according to signal intensity when monitoring.

TCD is used to evaluation of numerous neurological vascular diseases such as vasospasm and intracranial stenosis. It is also used for intraoperative monitoring to help detect sudden changes in flow and potential embolic events. Emboli are small particles of foreign matter (air, particulate, thrombin, etc.) within the bloodstream that can potentially cause obstructions in various arteries in the body and the brain. Such obstructions can often lead to stroke.

8. Non-Clinical Test Conclusion

Bench tests were conducted to verify that all the risks identified associated with the design change were acceptable. The tests include:

a) IEC 60601-1:2005 Ed3.0, Medical Electrical Equipment - Part 1: General Requirements for Safety;
b) IEC 60601-1-2:2007 Ed3.0, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests;
c) NEMA UD 2-2004 (R2009), Acoustic Output MeasurementStandard for Diagnostic Ultrasound Equipment Revision 3.

9. Substantially Equivalent Conclusion

The proposed device, Transcranial Doppler with Robotic Probe Headband, EMS 9UA and EMS9PB,are determined to be Substantially Equivalent (SE) to the predicate device (existed device), EMS9UA Transcranial Doppler with Robotic Probe Headband as cleared in K092164, in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 15, 2013

Shenzhen Delicate Electronics Co., Ltd.
c/o Ms. Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 237-023, Shanghai, 200237
CHINA

Re: K122710
Trade/Device Name: Transcranial Doppler with Robotic Probe Headband; Models: EMS9UA and EMS9PB
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, ITX, and OQQ
Dated: January 22, 2013
Received: January 25, 2013

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Transcranial Doppler with Robotic Probe Headband; Models: EMS9UA and EMS9PB, as described in your premarket notification:

Transducer Model Number

02.0001.0214.01	AP99-0607-PW2.0
02.0001.0213.01	02.0001.0408.01
02.0001.0805.01	02.0128.1616.01
AP99-0815-PW1.60	02.0001.1613.02

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

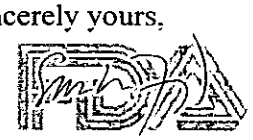
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,



for

Janine Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure(s)

Exhibit #2 Indications for Use

510(k) Number: K122710
Device Name: Transcranial Doppler with Robotic Probe Headband
Model: EMS9UA

Indications for Use:

Transcranial Doppler Ultrasound System is intended for use as a diagnostic ultrasound fluid flow analysis system:

1) For the measurement of cerebral artery blood velocities to determine the presence of hemo dynamically significant deviations from normal values;
2) To assess arterial cerebral blood flow for the occurrence of micro embolic signals. Vessels intended for observation include, but are not limited to the middle, anterior and posterior cerebral arteries, via the temporal windows, the vertebral mid basilar arteries via the foramen magnum and the ophthalmic artery and intracranial internal carotid artery via the eye.

The Roboprobe Headband facilitates monitoring use by its ability to track the Doppler signal.
Transcranial Doppler is intended for use during:

1) Diagnostic exams;
2) Surgical interventions.

The device is not intended to replace other means of evaluating vital patient physiological processes, is not intended to be used in fetal applications, and is not intended to be used inside the sterile field.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health

Diagnostic Ultrasound Indications for Use Form

SYSTEM: EMS9UA Transcranial Doppler with Robotic Probe Headband

Transducer: 02.0001.0214.01

Indented Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (track 1 Only)	Specific (Track 1 and Track 3)	A	B	M	PWD	CWD	Color Doppler	Combined (B/M)	Other (specify)
Ophthalimic	Ophthalmic				P				
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic				P				
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-Cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel				P				
	Other (specify)								

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Comments:

Diagnostic Ultrasound Indications for Use Form

SYSTEM: EMS9UA Transcranial Doppler with Robotic Probe Headband

Transducer: AP99-0607-PW2.0

Indented Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (track 1 Only)	Specific (Track 1 and Track 3)	A	B	M	PWD	CWD	Color Doppler	Combined (B/M)	Other (specify)
Ophthalimic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic				N				
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-Cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel				N				
	Other (specify)								

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Comments:

Diagnostic Ultrasound Indications for Use Form

SYSTEM: EMS9UA Transcranial Doppler with Robotic Probe Headband

Transducer: 02.0001.0213.01

Indented Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (track 1 Only)	Specific (Track 1 and Track 3)	A	B	M	PWD	CWD	Color Doppler	Combined (B/M)	Other (specify)
Ophthalimic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic				P				
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-Cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel				P				
	Other (specify)								

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Comments:

Diagnostic Ultrasound Indications for Use Form

SYSTEM: EMS9UA Transcranial Doppler with Robotic Probe Headband

Transducer: 02.0001.0408.01

Indented Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (track 1 Only)	Specific (Track 1 and Track 3)	A	B	M	PWD	CWD	Color Doppler	Combined (B/M)	Other (specify)
Ophthalimic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-Cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel					P			
	Other (specify)								

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Comments:

Diagnostic Ultrasound Indications for Use Form

SYSTEM: EMS9UA Transcranial Doppler with Robotic Probe Headband

Transducer: 02.0001.0805.01

Indented Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (track 1 Only)	Specific (Track 1 and Track 3)	A	B	M	PWD	CWD	Color Doppler	Combined (B/M)	Other (specify)
Ophthalimic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-Cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel					P			
	Other (specify)								

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Comments:

Indications for Use

510(k) Number: K122710
Device Name: Transcranial Doppler with Robotic Probe Headband
Model: EMS9PB

Indications for Use:

Transcranial Doppler Ultrasound System is intended for use as a diagnostic ultrasound fluid flow analysis system:

3) For the measurement of cerebral artery blood velocities to determine the presence of hemo dynamically significant deviations from normal values;
4) To assess arterial cerebral blood flow for the occurrence of micro embolic signals. Vessels intended for observation include, but are not limited to the middle, anterior and posterior cerebral arteries, via the temporal windows, the vertebral mid basilar arteries via the foramen magnum and the ophthalmic artery and intracranial internal carotid artery via the eye.

The Roboprobe Headband facilitates monitoring use by its ability to track the Doppler signal.
Transcranial Doppler is intended for use during:

3) Diagnostic exams;
4) Surgical interventions.

The device is not intended to replace other means of evaluating vital patient physiological processes, is not intended to be used in fetal applications, and is not intended to be used inside the sterile field.

☒PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☐OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Diagnostic Ultrasound Indications for Use Form

SYSTEM: EMS9PB Transcranial Doppler with Robotic Probe Headband

Transducer: 02.0128.1616.01

Indented Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (track 1 Only)	Specific (Track 1 and Track 3)	A	B	M	PWD	CWD	Color Doppler	Combined (B/M)	Other (specify)
Ophthalimic	Ophthalmic				N				
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic				N				
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-Cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel				N				
	Other (specify)								

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Comments:

Diagnostic Ultrasound Indications for Use Form

SYSTEM: EMS9PB Transcranial Doppler with Robotic Probe Headband

Transducer: AP99-0815-PW1.60

Indented Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (track 1 Only)	Specific (Track 1 and Track 3)	A	B	M	PWD	CWD	Color Doppler	Combined (B/M)	Other (specify)
Ophthalimic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic				N				
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-Cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel				N				
	Other (specify)								

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Comments:

Diagnostic Ultrasound Indications for Use Form

SYSTEM: EMS9PB Transcranial Doppler with Robotic Probe Headband

Transducer: 02.0001.1613.02

Indented Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (track 1 Only)	Specific (Track 1 and Track 3)	A	B	M	PWD	CWD	Color Doppler	Combined (B/M)	Other (specify)
Ophthalimic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic				N				
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-Cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel				N				
	Other (specify)								

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Comments:

Diagnostic Ultrasound Indications for Use Form

SYSTEM: EMS9PB Transcranial Doppler with Robotic Probe Headband

Transducer: 02.0001.0408.01

Indented Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (track 1 Only)	Specific (Track 1 and Track 3)	A	B	M	PWD	CWD	Color Doppler	Combined (B/M)	Other (specify)
Ophthalimic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (specify)								
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	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-Cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel					N			
	Other (specify)								

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Comments:

Diagnostic Ultrasound Indications for Use Form

SYSTEM: EMS9PB Transcranial Doppler with Robotic Probe Headband

Transducer: 02.0001.0805.01

Indented Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (track 1 Only)	Specific (Track 1 and Track 3)	A	B	M	PWD	CWD	Color Doppler	Combined (B/M)	Other (specify)
Ophthalimic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intraoperative (specify)								
	Intraoperative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
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	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-Cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel					N			
	Other (specify)								

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Comments:

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health